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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 09/163,199 | 09/30/1998 | HITOSHI FUKUSHIMA | 04783/026001 | 9722 |

7590 01/10/2003

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| EXAMINER |
|---|
| BAKER, MAURIE GARCIA |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1639 | |

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/163,199 | Fukushima et al |
| **Examiner** | **Art Unit** |
| Maurie G. Baker, Ph.D. | 1639 |

*-- Th MAILING DATE of this communication appears on th c ver sheet with the correspondenc address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *THREE* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1) ☒ Responsive to communication(s) filed on *Oct 25, 2002*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

**Disposition of Claims**

4) ☒ Claim(s) *1, 7, and 8* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 7, and 8* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

**Application Papers**

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). *29*
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

## DETAILED ACTION

**Please note**: The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to Art Unit **1639**.

### *Continued Prosecution Application*

1. The request filed on October 25, 2002 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No.: 09/163,199 is acceptable and a CPA has been established. An action on the CPA follows.

2. Applicant's Preliminary Amendment filed October 25, 2002 (Paper No. 28) is acknowledged. Claims 1 and 8 were amended. Currently, claims 1, 7 and 8 are pending and under examination.

### *Withdrawn Rejections*

3. The previous rejections under 35 U.S.C. 112, first paragraph have been withdrawn in view of applicant's claim amendments.

### *Claim Rejections - 35 USC § 112*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 7 and 8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed fails to support the invention as now claimed. Amended claim 1 recites that the sensor device has "a transducing element capable of transducing change in electric impedance in connection with absorbing aromatic molecules inside the organic film into electric signals". Applicant points to page 8 for support; however, the cited portions of the specification only provides general support for measuring changes in electric impedance of electrodes coated with a film. The examiner deems that this is **not** sufficient support for the specific limitation of having a "transducing element capable of transducing change in electric impedance in connection with absorbing aromatic molecules inside the organic film into electric signals". Note that a broad generic disclosure is not sufficient support for a specific entity within the class.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 7 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Amended claim 1 recites the limitation in step (b) of "ejecting the solution via the ink jet nozzle to rest on the microelectrodes". This limitation is confusing and renders the claims indefinite. It is simply unclear what "ejecting the solution ... to rest on the microelectrodes" would entail. That is, applicant's intent is unclear. This is especially true when the step of printing earlier in the claim recites printing a solution onto the surfaces of the microelectrodes "such that organic thin films are formed on the microelectrodes". Is this the same as "ejecting the solution ... to rest on the microelectrodes"? For the purposes of this Office Action, the step of "ejecting the solution via the ink jet nozzle to rest on the microelectrodes" is interpreted as simply creating an organic thin film on the microelectrode.

B. Amended claim 1 also recites that the sensor device has "a transducing element capable of transducing change in electric impedance in connection with absorbing aromatic molecules inside the organic film into electric signals". It is unclear how "a transducing element" is to be "capable of" trandsducing under the conditions specified since the specific transducing element is not set forth in the claim. See MPEP § 2173.02: If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973). Moreover, the claim could be considered as being incomplete for omitting essential elements (i.e. transducing element "capable of" ...), such omission amounting to a gap between the elements. See MPEP § 2172.01.

*Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musho et al (US 5,250,439; of record) in view of Hayes et al (US 4,877,745).

Please note: For the purposes of this rejection, *any* transducing element is deemed to be "capable of transducing change in electric impedance in connection with absorbing aromatic molecules inside the organic film into electric signals". The instant claims and specification are silent as to the specifics required for such an element. The Office does not have the facilities to make a comparison and the burden is on the applicants to establish any difference between the transducing elements of the art and the instant

claims. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). See also rejection under 35 U.S.C. 112, second paragraph above.

Musho et al teach a conductive sensor and use in diagnostic assay where the sensor is miniaturized and uses a conducting polymer (see Abstract). The sensors "utilize the unique electrical properties of conducting polymers to determine the presence and concentration of a predetermined analyte" (see column 12, lines 9-12) and are based on "the oxidative doping of a conducting polymer" such as a polythiophene (see column 16, line 58-63, for example). The conductive sensor "allows an accurate and sensitive electrical transduction of an analyte-oxidase interaction" (see column 12, lines 48-50) reading on the transducing element of the instant claims. Specifically, Figure 2 of the reference shows microelectrodes having a "gap" filled with conducting polymer. This polymer is applied as a "thin, uniform layer or film" (see column 21, lines 55-61, for example). The conductive polymers used by Musho are especially chosen for their processibility in solution and can be applied by ink-jet printing (see column 22, lines 49-65). See especially column 31, lines 53-65 which discusses the manufacture of the sensors using conductive polymers in solution. As an organic thin film is made on the microelectrodes of the reference, this is deemed to read on the limitation in step (b) of "ejecting the solution via the ink jet nozzle to rest on the microelectrodes". Using plastic as a base is also disclosed, see column 41, lines 1-2, reading on claim 7.

With respect to the limitation that the solution has a viscosity "of about 3 centipoise or less", it is noted that "[p]roducts of identical chemical composition can not

have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Since the reference discloses a solution comprising "an electro-conductive polymer and a solvent" as set forth in the claims, this solution is deemed to have the properties applicant discloses.

Musho et al lacks the specific teachings with respect to the ink jet nozzle and operation of the ink jet (i.e. step (a)).

However, these teachings simply represent the standard operation of an ink jet printing device that were well-established in the art at the time of filing. For example, Hayes et al teach "a system for printing and dispensing chemical reagents" using a "jetting tube" which is "mounted within a cylindrical piezo-electric transducer" (see Abstract and Figures 1-4 & 6-8 and accompanying text). An electrical signal is applied to the transducer which causes an expansion (and drawing in of fluid) and when the signal is stopped, a de-expansion, thus ejecting the fluid as a droplet (also see Abstract). This reads directly on the limitations set forth for the ink jet nozzle (i.e. deformation of piezo-electric element) and those in step (a) of instant claim 1. Moreover, Hayes et al teaches that an advantage of using ink jet printing of reagents is that "precise minute quantities of reagent fluid may be dispensed or printed in a reproducible manner" and that "the method and apparatus may be used to emit droplets of fluids having a wide range of reagent fluid viscosities and surface tensions" (column 3, lines 44-51).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to use the standard methodology for ink jet printing in the creation of the sensors of Musho et al. One of ordinary skill would be motivated to do so since Musho et al specifically recites that the conductive polymers used in their sensors can be applied by ink-jet printing and the technology of ink jet printing of chemical reagents was well established in the art as taught by Hayes et al. One would also be motivated to use ink jet printing for manufacturing sensors with thin films thereon due to the known advantages of such a technique. These advantages are taught in Hayes et al, see above.

11. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (US 5,571,401; of record) in view of Hayes et al (US 4,877,745).

Please note: For the purposes of this rejection, *any* transducing element is deemed to be "capable of transducing change in electric impedance in connection with absorbing aromatic molecules inside the organic film into electric signals". The instant claims and specification are silent as to the specifics required for such an element. The Office does not have the facilities to make a comparison and the burden is on the applicants to establish any difference between the transducing elements of the art and the instant claims. See *In re Best,* 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and *Ex parte Gray*, 10 USPQ 2d 1922 1923 (PTO Bd. Pat. App. & Int.). See also rejection under 35 U.S.C. 112, second paragraph above.

Lewis et al teach chemical sensors for detecting analytes in fluids (see Abstract and Figures 1A-B). These sensors contain nonconductive and conductive materials; the

conductors can be organic conductors such as polymers (see column 4, lines 20-27). The materials can both be soluble in a common solvent, see column 5, especially lines 14-54 regarding the conductive polymer poly(pyrrole). The resistance of the film changes upon sorption of an analyte, thus transducing the interaction into an electrical signal (reading on the transducing element of the instant claims), see column 6, lines 9-28, for example. Fabrication of sensors using poly(pyrrole) is specifically disclosed, see column 8, lines 34-54. Lewis teaches that sensor arrays can be scaled up to IC design technologies and can be produced by ink-jet technology (column 6, lines 47-67).

With respect to the limitation that the solution has a viscosity "of about 3 centipoise or less", it is noted that "[p]roducts of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Since the reference discloses a solution comprising "an electro-conductive polymer and a solvent" as set forth in the claims, this solution is deemed to have the properties applicant discloses.

Lewis et al lacks the specific teachings with respect to the ink jet nozzle and operation of the ink jet (i.e. step (a)).

However, these teachings simply represent the standard operation of an ink jet printing device that were well-established in the art at the time of filing. For example, Hayes et al teach "a system for printing and dispensing chemical reagents" using a "jetting tube" which is "mounted within a cylindrical piezo-electric transducer" (see

Abstract and Figures 1-4 & 6-8 and accompanying text). An electrical signal is applied to the transducer which causes an expansion (and drawing in of fluid) and when the signal is stopped, a de-expansion, thus ejecting the fluid as a droplet (also see Abstract). This reads directly on the limitations set forth for the ink jet nozzle (i.e. deformation of piezo-electric element) and those in step (a) of instant claim 1. Moreover, Hayes et al teaches that an advantage of using ink jet printing of reagents is that "precise minute quantities of reagent fluid may be dispensed or printed in a reproducible manner" and that "the method and apparatus may be used to emit droplets of fluids having a wide range of reagent fluid viscosities and surface tensions" (column 3, lines 44-51).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art to use the standard methodology for ink jet printing in the creation of the sensors of Lewis et al. One of ordinary skill would be motivated to do so since Lewis et al specifically recites their sensors can be can be produced by ink-jet printing and the technology of ink jet printing of chemical reagents was well established in the art as taught by Hayes et al. One would also be motivated to use ink jet printing for manufacturing sensors with thin films thereon due to the known advantages of such a technique. These advantages are taught in Hayes et al, see above.

12. Claims 1, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Musho et al (US 5,250,439; of record) in view of Hayes et al (US 4,877,745) and further in view of Smith et al (US 4,874,499).

The teachings of Musho et al and Hayes et al are set forth in the rejection above (paragraph 10).

The references lack the teaching of specifically using poly-silicon thin film transistors in the sensor (i.e., claim 8). However, such thin film transistors were well established in the art at the time of filing. For example, Smith et al teach the formation of electrochemical microsensors that can be formed from a wide variety of materials (for both the substrate and overlying structure) (see Abstract). Conventional integrated circuit processing techniques can be used and essentially "any means for sensing and transmitting potential or current from the sensing site can be utilized" including FETs having polysilicon gates (see column 6, lines 1-25, for example). Moreover, a variety of substrates can be used for the microsensors, including organic resins (column 6, lines 33-38).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use art-standard poly-silicon thin film transistors in the sensors of Musho et al. One of ordinary skill would have been motivated to do so in order to be able to use art-standard circuitry and conventional integrated circuit processing techniques in the manufacture of such microsensors.

13. Claims 1, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lewis et al (US 5,571,401; of record) in view of Hayes et al (US 4,877,745) and further in view of Smith et al (US 4,874,499).

The teachings of Lewis et al and Hayes et al are set forth in the rejection above (paragraph 11).

The references lack the teaching of specifically using poly-silicon thin film transistors in the sensor (i.e., claim 8). However, such thin film transistors were well established in the art at the time of filing. For example, Smith et al teach the formation of electrochemical microsensors that can be formed from a wide variety of materials (for both the substrate and overlying structure) (see Abstract). Conventional integrated circuit processing techniques can be used and essentially "any means for sensing and transmitting potential or current from the sensing site can be utilized" including FETs having polysilicon gates (see column 6, lines 1-25, for example). Moreover, a variety of substrates can be used for the microsensors, including organic resins (column 6, lines 33-38).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to use art-standard poly-silicon thin film transistors in the sensors of Lewis et al. One of ordinary skill would have been motivated to do so in order to be able to use art-standard circuitry and conventional integrated circuit processing techniques in the manufacture of such microsensors.

***Status of Claims/ Conclusion***

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
January 7, 2003

**MAURIE GARCIA BAKER, Ph.D.**
**PATENT EXAMINER**